DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

#32

Re: Reality™ Female Condom
Docket No. 93E-0290

MAY - 2 1994

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner for Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,735,621, filed by Chartex International Plc, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for the Reality™ Female Condom, the medical device claimed by the patent.

The total length of the review period for Reality™ Female Condom is 2,017 days. Of this time, 1,460 days occurred during the testing phase and 557 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date on which the first clinical trial on the device was begun: October 31, 1987.

   The clinical trial cited by the applicant was conducted outside the U.S. and was not subject to FDA's requirement for an investigational device execmption (IDE) under section 520(g) of the Federal Food, Drug and Cosmetic Act ("Act") nor to FDA's requirement for an institutional review board (IRB) approval under section 520(g)(3) of the Act. Therefore, the testing phase begins on the date the device is first used with human subjects as part of a clinical investigation to be filed with FDA to secure premarket approval of the device. 21 CFR 60.22(c)(1)(iii). The applicant has stated that the date on which the device was first used with human subjects as part of a clinical investigation to be filed with the FDA to secure premarket approval of the device was October 31, 1987. Although FDA lacks the records to be able to confirm that testing began as stated by the applicant, FDA is using this date as the start of the testing phase.

2. The date the application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act: October 29, 1991.

   FDA has verified the applicant's claim that the PMA P910064 was initially submitted on October 29, 1991.

3. The date the application was approved: May 7, 1993. FDA has verified the applicant's claim that PMA P910064 was approved on May 7, 1993.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Paul Grandinetti, Esq.
Levy, Zito & Grandinetti
1910 K Street N.W., Suite 411
Washington, D.C. 20006